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Retrospective Policy Analysis of Kentucky House Bill 1

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Dr. Teresa Waters, Committee Chair

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Retrospective Policy Analysis of Kentucky House Bill 1

A paper submitted in partial fulfillment of the requirements for the degree of Master
of Public Health in the University of Kentucky College of Public Health by
Sarah E. B. Covey

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To my husband, Matthew, who has always encouraged me to pursue my dreams, even when the odds were against me. Thank you for being a full-time physician, and doing the dishes, for treating patients, and vacuuming the floors, for working at the hospital, and working some more at home. I can't express my gratitude and pride to be your wife.

Finally, no amount of planning, talent, or hard work on my part could make possible any significant or fulfilling achievement without the help of God. I am especially grateful for all my family and friends who have prayed for and with me to get me through this journey.

*Plans fail for lack of counsel, but with many advisers they succeed.
- Proverbs 15:22*

ABSTRACT

Background: In 2011, the Centers for Disease Control (CDC) coined the phrase, “opioid epidemic” in response to the staggering increase in opioid use and opioid-related deaths. Kentucky House Bill 1 (HB1) passed in 2012, attempted to stifle the impact of the opioid epidemic on the citizens of the Commonwealth by imposing supply-side restrictions on the prescription and dispensing of opioid pills. Objective: The primary objective of this analysis is to evaluate the effectiveness of HB1 on the reduction of opioid-related deaths, opioid prescription rates, and intravenous opioid drug use rates. Methods: This analysis employed Eugene Bardach’s framework for policy analysis- the Eightfold Path, to systematically assess the policy and other options at that time. Results: After HB1 a decrease in the rate of opioid prescriptions in Kentucky was observed. However, the rate of opioid-related overdose deaths increased. Discussion/Recommendation: Supply-side restrictions on opioid pills may lead to the unintended consequence of diversion to intravenous opioid abuse, which carries even greater public health implications. Comprehensive policy should include both supply-side regulations as well as provisions for treatment and recovery for those suffering from addiction.

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Introduction

With hundreds of people dying each year of opioid-related overdoses, states in the US are desperately seeking effective strategies to curb the consequences of the opioid epidemic. Now more than ever, smart laws and practical policies are essential to quell the devastation found across the nation. Kentucky has suffered significant loss during the last decade, and state legislators continually hope to provide solutions for their constituents.

This is a retrospective policy analysis of Kentucky House Bill 1 (HB1), passed in 2012, which attempted to stifle the impact of the opioid epidemic on the citizens of the Commonwealth by imposing supply-side restrictions on the prescription and dispensing of opioid pills. The primary objective of the analysis is to evaluate the effectiveness of HB1 on the reduction of opioid-related deaths, opioid prescription rates, and intravenous opioid drug use rates.

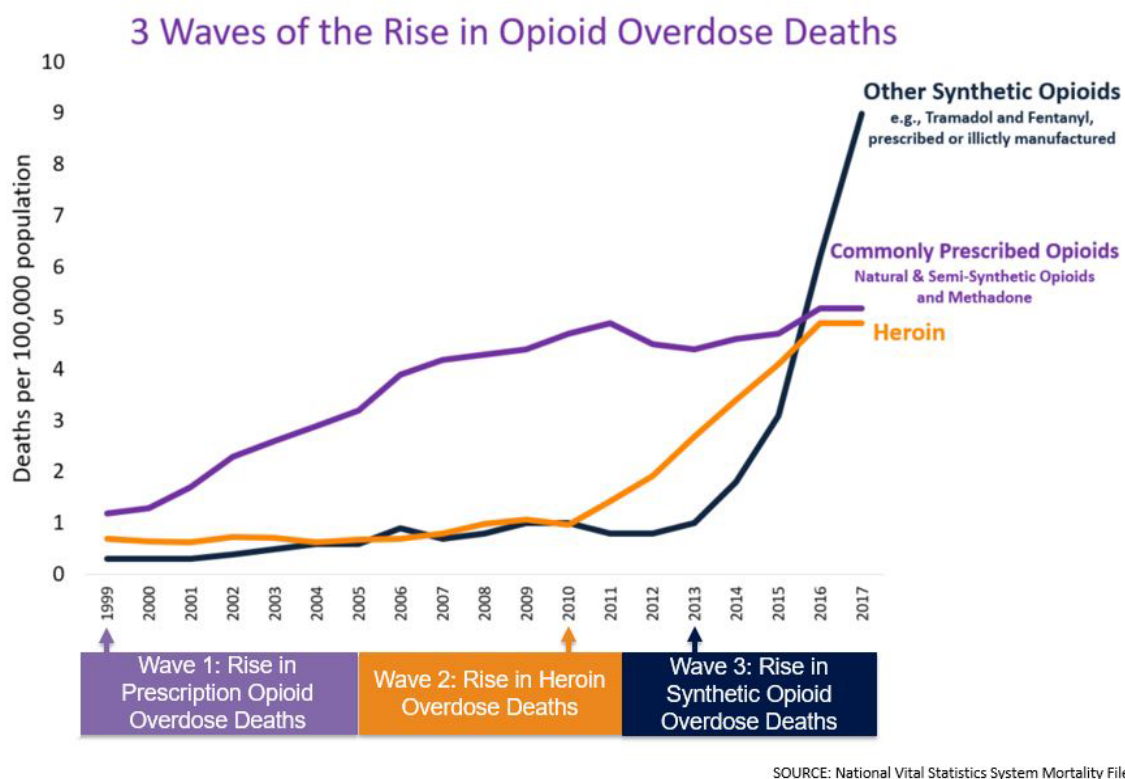
Background

The Opioid Epidemic

In 2011, the Centers for Disease Control (CDC) coined the phrase, “opioid epidemic” in response to the staggering increase in opioid use and opioid-related deaths. This was not the first wave of opioid-related deaths, however. In the late 1990s, Purdue and other pharmaceuticals began marketing prescription opioids to physicians for the use of non-cancer-related pain, claiming that they had a low risk of dependence.¹ This resulted in an increase in prescriptions, addiction, diversion (distributing prescription pills to non-prescribed users), and opioid-related overdoses.² For

unknown reasons, another spike in opioid misuse and overdose rates occurred in 2010. This time, rather than an increase in prescription opioid drugs, a surge in heroin was observed. A third wave occurred around 2013, when misuse of synthetic opioids, e.g. Fentanyl, increased rapidly (see figure 1).

Figure 1. 3 Waves of the Rise in Opioid Overdose Deaths



To understand the factors contributing to the epidemic, one must consider the pharmacology of opioids. Opioids are so-named because they target opioid receptors found along the nervous system. Humans create endogenous opioids in fact, called endorphins and enkephalins, which are responsible for the famed “runner’s high”.³ Opioids are also found outside the body, as naturally occurring substances found in the poppy flower, or manufactured synthetic drugs. When

opioid substances bind to opioid receptors, a response is triggered that inhibits the transmission of pain signals to the brain.

Opioids are not only highly effective analgesics (painkillers), but they also activate dopaminergic receptors, resulting in a pleasurable response that can potentially reinforce its use. Different opioids elicit varying levels of pleasurable sensations. In addition, an individual's genetics also play a role in how pleasant a drug seems, which is termed "drug liking".³

Opioids are the most potent painkillers in the practitioner's arsenal, and were historically used to treat end-of-life pain in cancer patients. Around 1999, the practice of prescribing opioids for non-cancer pain became more common. They were, and are still, the drug of choice for post-surgery patients and trauma victims. However, at the turn of the century, prescribers began writing opioid prescriptions for chronic pain, and it was at this time that the rise in misuse was observed. Contrary to the pharmaceutical companies' claims, opioids can be highly addictive substances.

Opioid addiction can be attributed to two pharmacological concepts: tolerance and dependence. First, the term tolerance refers to the expected phenomenon of requiring higher dosages to achieve the same effect.³ For example, a person may require a certain amount of oxycodone to relieve their lower back pain, but in a few weeks, even days, may require an increased dose to relieve that same pain. For this reason, a patient in this scenario could be described as suffering from "pseudo-addiction," but tolerance is a known and expected occurrence. The second concept is physical dependence. This is the manifestation of unpleasant

withdrawal symptoms upon the abrupt cessation of drug use, commonly referred to as “addiction.” ³

While the majority of prescription pain-reliever users do not misuse them, ⁴ their misuse has significant implications for public health. Physical dependence may account for the majority of adults who have misused prescription pain relievers reporting in 2015 that they misuse them to relieve physical pain (see figures 2 and 3). ⁵ Only 11.7% reported misusing to “feel good or get high.” ⁵

Figure 2. Past year misuse of prescription pain relievers among adults aged 18 or older: 2015

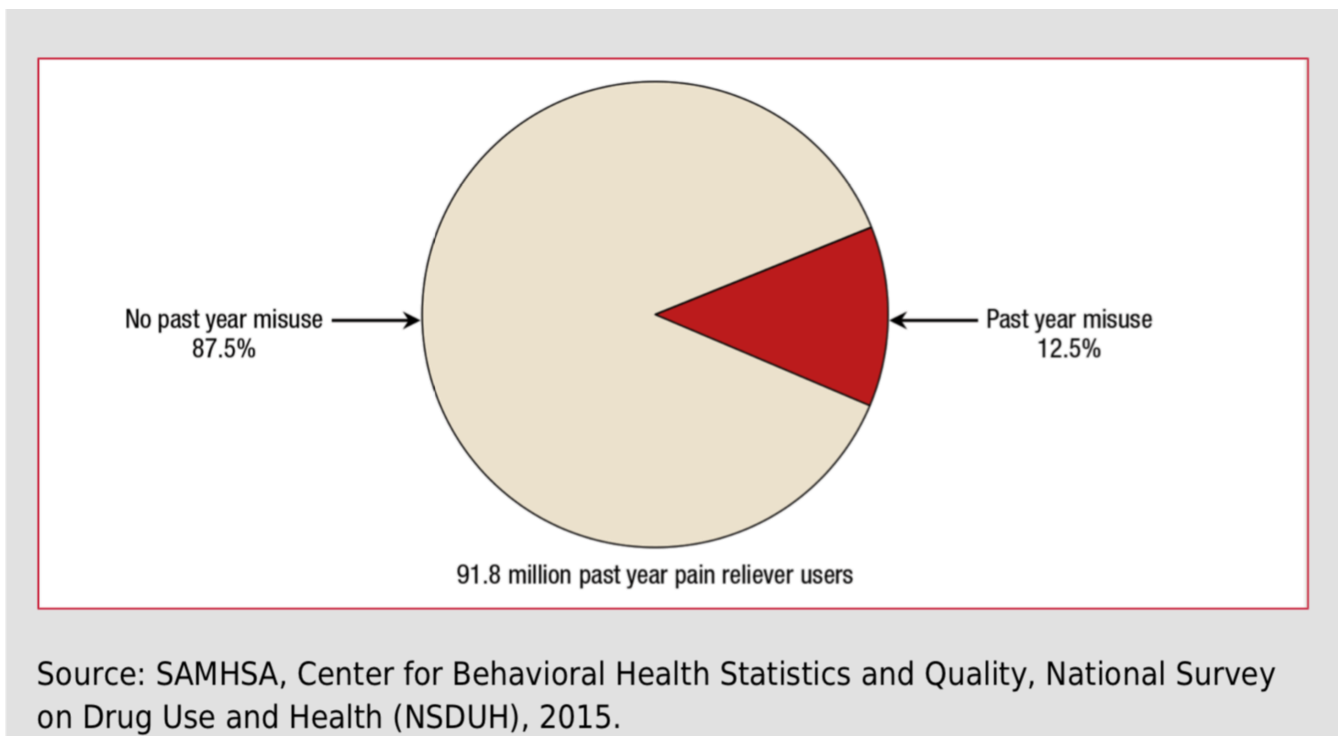
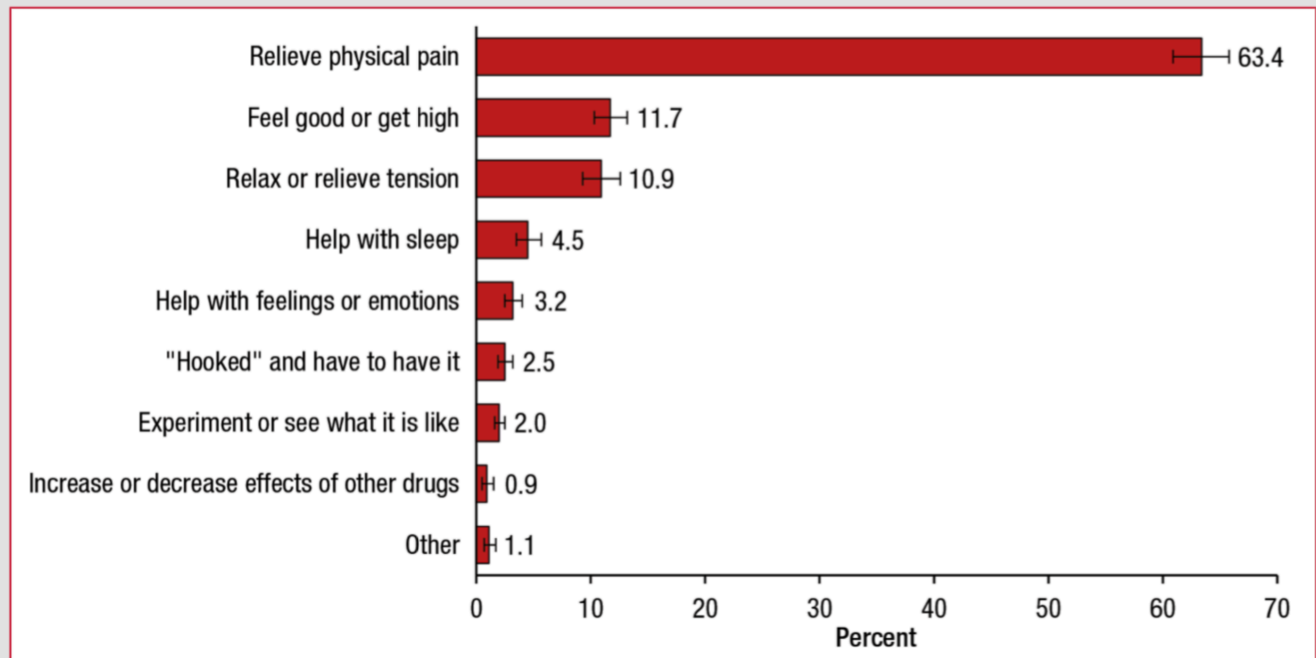


Figure 3. Main reasons for last episode of prescription pain reliever misuse among past year misusers ages 18 or older: 2015



Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health (NSDUH), 2015.

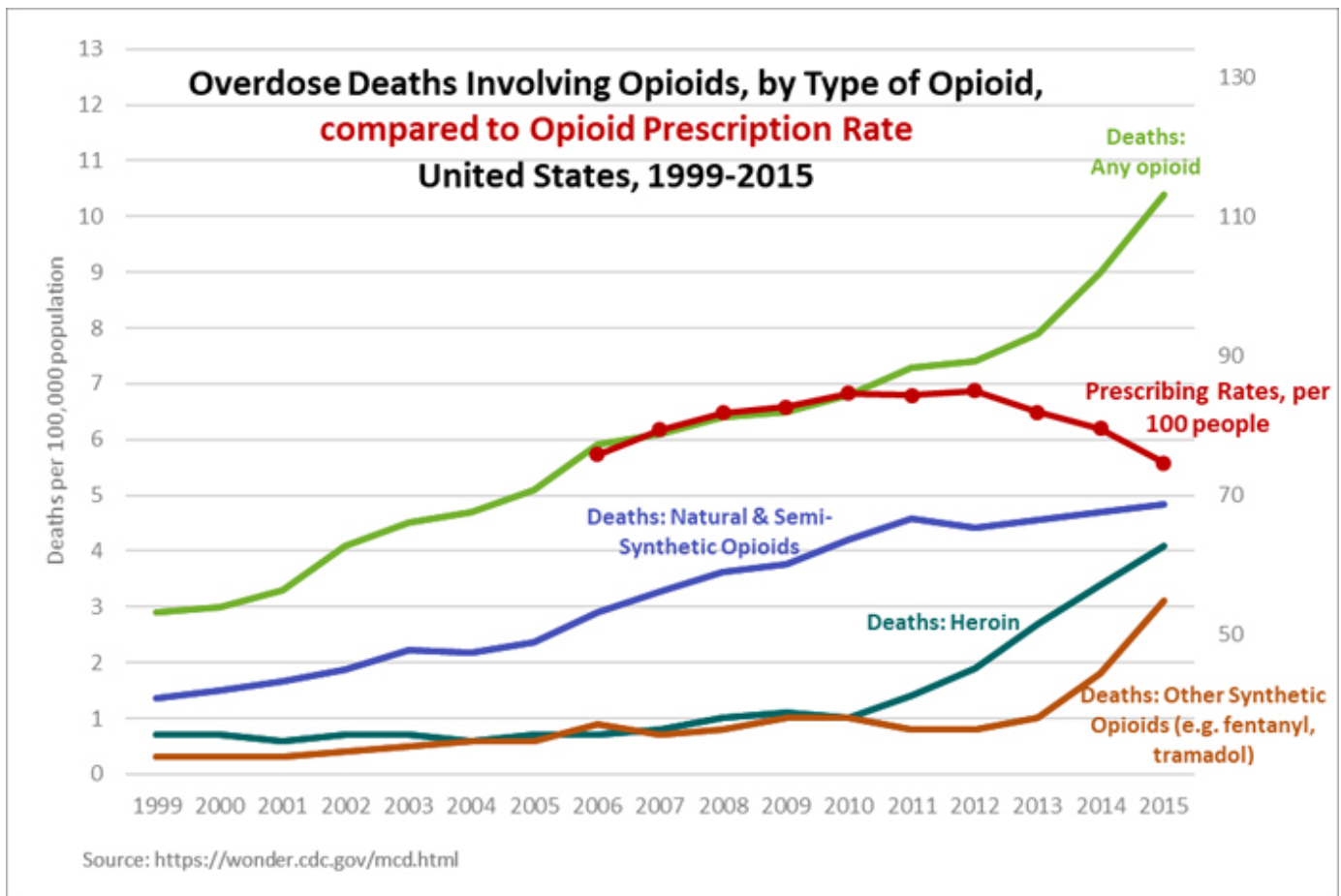
Because of analgesic and pleasure-eliciting properties of opioids, humans have created multiple ways to use them. Methods of intake include oral pills, intravenous injection or infusion, subcutaneous injection (ie. skin popping), snorting powders, and smoking. ⁶

Opioid Overdose Deaths

Opioids have a depressant effect on the nervous system, which results in the common side effects of nausea, vomiting, and constipation, as well as more alarming results including sedation and respiratory depression. Rates of overdose, which

simply refers to the taking of a dangerous amount of substance, have continually increased each year over the last decade and a half, despite prescription rates decreasing (see figure 4).⁷

Figure 4. Overdose deaths involving opioids, by type of opioid, compared to opioid prescription rate

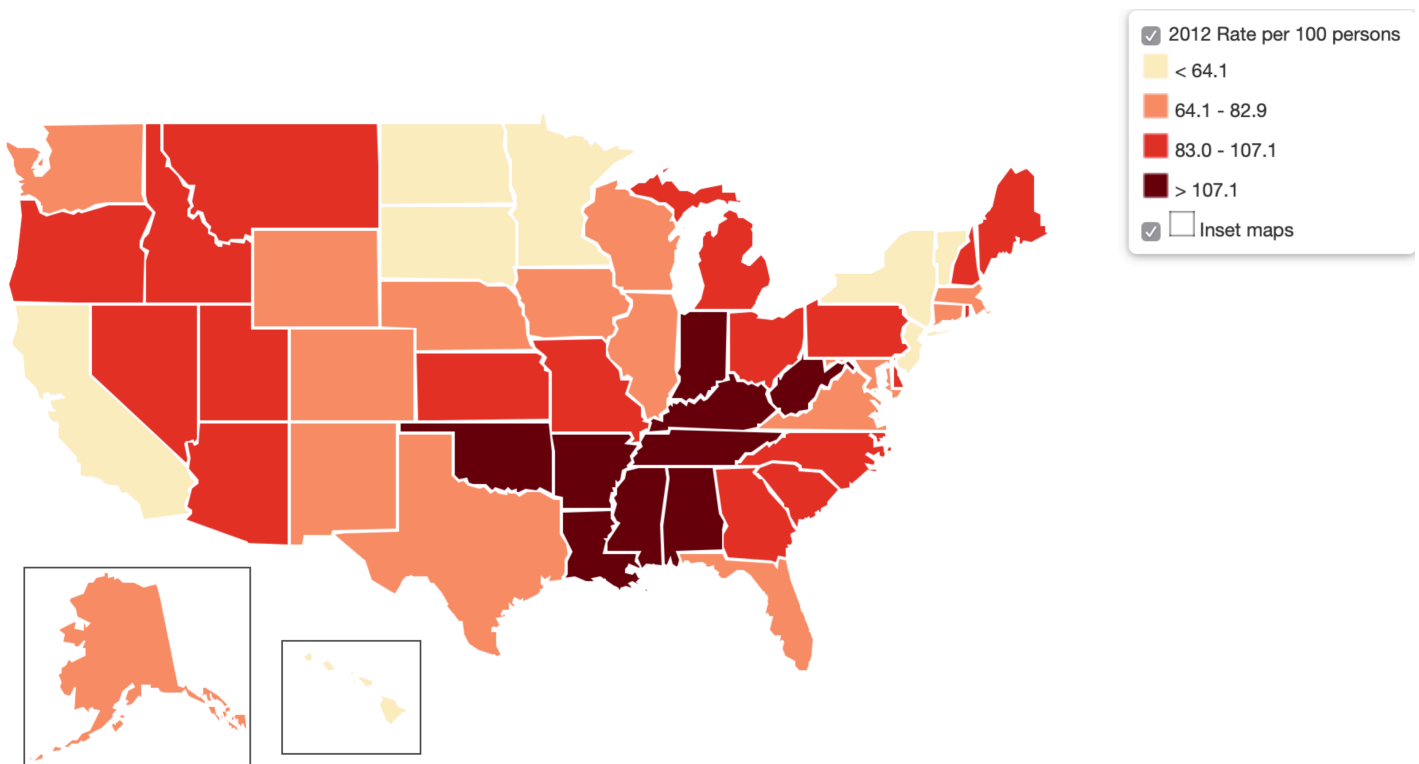


The Opioid Epidemic in Kentucky

Kentucky has not been spared the devastation of the opioid crisis, in fact it is an epicenter of opioid misuse. In 2017 alone, 1,565 people in the Commonwealth died of overdoses, with opioids causing the vast majority.⁸ The number of overdose deaths in Kentucky has increased each year for the past decade.

While the average opioid prescription rate in 2012 in the US was 81.3 prescriptions per 100 persons; in Kentucky, the rate was 127.9 per 100 persons (see figure 5).⁹

Figure 5. U.S. State Opioid Prescribing Rates, 2012



House Bill 1

To address the opioid crisis, Kentucky House Bill 1 was passed in the 2012 Special Session. It imposed restrictions on pain clinics and stricter licensing board regulations. HB1 also added requirements for physicians who prescribe schedule 2 and 3 drugs, and increased regulations regarding the electronic prescription record (i.e. KASPER) usage and access.¹⁰ It also mandated an annual report, which would detail the number of drug-related deaths, the drugs involved, the method by which

the drugs were obtained, and statistics regarding the demographics of the decedents.

Methods

An objective policy analysis will employ a framework to offer an unbiased assessment and to be pertinent to audiences of all opinions and credos. For this analysis, the Eightfold Path method put forward by Eugene Bardach at the University of California at Berkeley was employed.

Bardach's Eightfold Path

Bardach created a schema by which to systematically approach the task of analyzing a policy. This Eightfold Path method consists of a series of actions to guide one's analysis.

The first step is "Define the problem," in which the analyst focuses on the reason for the policy in question. The second step is "Assemble some evidence." Here, the analyst must gather data that inform the circumstances and facets of the problem. The third step is to "Construct the alternatives" wherein one considers other options that are available to address the problem. The fourth step is to "Select the criteria" by which the analyst will judge the outcomes of each alternative. The fifth step is to "Project the outcomes" of each alternative. However, for this retrospective analysis, the actual outcomes that occurred will be examined. The sixth step is to "Confront the trade-offs," weighing the pros and cons of the outcomes of each alternative. The seventh step is to "Stop, focus, narrow, deepen,

decide!” During this step the analyst must hone in on the best few options and dig deeper into them to decide which is the optimal choice. The last step is to “Tell your story,” communicating the results of the analysis to the target audience.

Bardach’s Eight-fold Path for Policy Analysis

Step	Brief Description of Action
1. Define the problem	Explain the impetus for the policy
2. Assemble some evidence	Gather the data surrounding the problem
3. Construct the alternatives	Describe the other possible options available
4. Select the criteria	Define the standards by which the options will be judged
5. Project the outcomes	Examine the results of the policy options
6. Confront the trade-offs	Weight the pros and cons of each alternative
7. Stop, focus, narrow, deepen, decide!	Consider more closely the best few options
8. Tell your story	Communicate the policy analysis results to target audience

Literature Review

The literature review included searching databases, PubMed and Google Scholar, by using the following terms and phrases: opioid epidemic (+/- in the United States or in Kentucky), opioid overdose (+/- in the United States or in Kentucky), opioid-related deaths in the United States, heroin-related deaths, heroin-related overdose, IV opioid usage rates (+/- in the United States or in Kentucky), heroin usage rates (+/- in the United States or in Kentucky), opioid drug abuse (+/- in the United States or in Kentucky), Kentucky House Bill 1.

Results

The first two steps in Bardach's Eightfold Path were addressed in the introduction portion of this paper. The problem was defined as the opioid epidemic in Kentucky, and the evidence gathered included a description of the rates of opioid morbidity and mortality in Kentucky and the United States at large, as well as a portrayal of the Kentucky House Bill 1 in the 2012 Special Session. Here, the remaining steps will be examined.

Construct the Alternatives

Base Case:

The base case is the policy enacted by the State Legislature of Kentucky in 2012, House Bill 1 (KY HB 1). This bill enacted restrictions on the supply-side of the opioid crisis, including multiple restrictions and requirements related to prescription and procurement of opioid pills. Specifically, it required pain management clinics to have a fully-licensed Medical Doctor (M.D) working in a clinical capacity at least 50% of the time, to be owned by an M.D., unless grandfathered-in, and to accept insurance plans.¹² It also encouraged inter-agency reporting of drug infractions, and mandated that any licensed prescriber who was found to be prescribing unlawfully be reported to the Commonwealth's Attorney General. The Bill also required various licensure boards, including Medical, Nursing, Dentistry, Optometry, and Podiatry, to regulate prescribing standards for controlled substances. This included a 48-hour limit for Schedule II and III hydrocodone substances, emergency suspension if licensee found to have dangerous prescription patterns, expedited investigation of

any allegations of unlawful prescribing by licensee, mandatory reporting of past convictions related to prescribing controlled substances, and requiring that 7.5% of licensee's continuing medical education includes training on addiction disorders and pain management. Finally, the bill mandates an annual report be published each year detailing the number and type of controlled substance overdoses and deaths, per county.

The remaining alternatives were the policies enacted by three states surrounding Kentucky: Ohio and Tennessee. These three states were chosen because they are located in the Appalachian region, and because of their similarities to Kentucky in population, socio-economic status, and culture.

Alternative 1:

The first alternative to be examined is the *null* alternative. This is the option of doing nothing, maintaining the status quo. This alternative opts not to interject policy change, but rather see how things “shake out.”

Alternative 2:

The third alternative is the policy enacted by the State Legislature of Tennessee, Senate Bill 2253, The Tennessee Prescription Safety Act of 2012 (TPSA). Similarly to KY HB1, TPSA imposes supply-side regulations to decrease the number of opioid prescriptions. It states that every practitioner and pharmacy must submit data to a controlled substance database each business day.¹³ Interestingly, it includes veterinarians in this, with the caveat that they have seven days to report to a non-

computer-based reporting system. In addition, each provider must look at the database before prescribing controlled substances to their patient for the first time, and then annually after that, or in the case the provider suspects the patient of drug-seeking behavior for the intent of abuse. The only exception to this is in the case of prescribing controlled substances in a non-refillable manner for the treatment of pain following a surgical procedure, not to exceed a single 7-day course of treatment.

Alternative 3:

In contrast to the previous two legislative bills, the fourth alternative was an executive action. Governor Kasich created the Governor's Cabinet Opiate Action Team in 2011 to address the early opioid epidemic in Ohio. This 75-member, multidisciplinary task force, led jointly by physicians and policymakers, then implemented multiple regulations. These included guidelines "created by and for prescribers" across three different prescribing scenarios: patient care in emergency department/acute care centers, management of chronic pain, and management of acute pain, such as in the post-operative period.¹⁴ The GCOAT also "encouraged" providers to consult the Prescription Drug Monitoring Program (PDMP) before prescribing opioids. The goals of these regulations were to encourage responsible prescription of opioids, emphasize preventing drug abuse, and improve access to treatment.¹⁵ In an effort to reduce the number of clinics that improperly dispense opioid prescriptions, "pill mills," the GCOAT made it mandatory for the Ohio Board of Pharmacy to license all pain medicine clinics and illegal for any convicted felon to

own or operate one. The GCOAT also initiated a “drug take-back” program, wherein drop boxes were provided around the state for the disposal of unused medications.

Select the Criteria

Three criteria were chosen to evaluate policy impact: efficacy, justice, and freedom. For this study, the *efficacy* refers to a policy’s ability to impact/reduce: the rate of prescription of opioid pills and the rate of opioid-related overdose deaths. For this analysis, a policy that exhibits *freedom* is one in which the fewest regulations and restrictions are imposed in order to reap the greatest benefits. Ideally, a policy would enact only those regulations and restrictions that are necessary to achieve effective results. *Justice* refers to the equal distribution of restrictions and benefits. For example, a hypothetical policy that heavily restricts one group of people while benefiting another group of people would not meet the justice criteria. Not only should a policy employ the fewest regulations and restrictions and produce the greatest benefit possible, but those regulations, restrictions, and benefits should be equally disbursed.¹⁶

Examine the Outcomes, Confront the Trade-offs

In order to be as objective as possible, a criteria-alternatives matrix (CAM) will be employed. This will include examining each alternative as it relates to the criteria listed above and evaluating how well each policy alternative fulfills each criterion.

Each criterion will be given a weight, such that they add up to 1.0, and each policy will be awarded a rating value for each criterion on a scale of 1-4.

Weighting of Criteria

Of the three criteria, Criterion 1: Efficacy will be weighed highest at 0.4. The reason behind the heavy weighting is that the goal of the policy is to address the problem of addiction. Since it is nearly impossible to quantify addiction, two measures that approximate the problem, rates of opioid prescriptions and rates of opioid-related overdose deaths were used.

Criterion 2: Freedom and Criterion 3: Justice will be weighted at 0.3 each. This is a subjective and highly politically charged ideal, and readers may disagree with the weight, whether that it may be too high or too low. However, for this analysis, freedom and justice will be weighed equally, as they are both considered to be essential for the average American citizen. As it is stated in the Declaration of Independence, liberty is an unalienable right in the United States. It is the position of this analysis that the law governing each citizen should be no more restrictive than is necessary to achieve a solution that is just. A policy that unduly restricts one group of citizens while providing benefits to another group is neither fair nor just, but it also disproportionately infringes on the freedom of the restricted group.

Table 1: Criterion Weightings	
Criterion 1: Efficacy	0.4
Criterion 2: Freedom	0.3
Criterion 3: Justice	0.3
Total	1

Table 2: Rating Values	
Rating	Value
Does Not Satisfy Criteria	1
Minimally Satisfies Criteria	2
Moderately Satisfies Criteria	3
Satisfies Criteria	4

Base Case:

Efficacy:

How effective was KY HB1 at decreasing opioid prescriptions, overdoses, and deaths? According to the CDC, in 2011, Kentucky had an opioid prescription rate of 127.9 prescriptions per 100 persons. This dropped to 110.0 per 100 persons in 2015.¹⁷ However, the opioid-related overdose death rate increased from 15.8 per 100,000 persons in 2011 to 21 per 100,000 persons.¹⁸ It is posited that the increase in opioid-related deaths in the setting of prescription opioid supply regulations demonstrates a shift of abuse towards the less expensive and more easily obtainable “street” opioids such as heroin. This will be discussed in a later section.

Freedom:

As for the criterion of freedom, KY HB1 introduced restrictions on physicians and other opioid prescribing providers and distributors. It created more “hoops” for providers to jump through in order to get their patients the pain-relief they needed. Some providers seem grateful for the increased restrictions, as it allowed them to limit access to opioids to patients they believe no longer need them without being

the “bad guy,” while others complained it has been difficult to give their patients adequate pain relief given these regulations.

Justice:

The last criterion, justice, will be examined based on how the benefits and consequences were distributed among residents of Kentucky. The restrictions of KY HB1 limited the accessibility of prescription opioids to both the people who used them legally and illicitly. Many providers may feel that the onus has been put on them to regulate access to prescription opioid pills, while the consequences for those who are already addicted are not being addressed.

Alternative 1:

Efficacy:

While it was impossible to predict the exact rates of opioid prescriptions and overdose deaths, for this study, a trend line based on the five years prior to the base case was used to extrapolate these rates. Based on this extrapolation, the opioid prescription rate in 2015 given the status quo would be approximately 139.5, and the opioid-related overdose rate would be 17.3 (see Figures 6 and 7).

Freedom:

The status quo alternative, wherein there is no additional policy enacted, and therefore no imposed restrictions, seems to easily fulfill the criterion of freedom. However, one may argue that the lack of regulations leaves a number of citizens at greater risk of harm and thus decreases their freedom. For example, those patients who should not be on prescription opioid pills, but are given them by their

physician, and who later become addicted will suffer a lack of freedom because of this, whether that be in the form of hospitalization or fatality.

Justice:

This alternative, while imposing no legal restrictions, also gives little legal protections for those who would be impacted by opioid addiction. One group of citizens may benefit more greatly than another in this scenario. For example, the costs associated with emergency services and hospitalizations for those who abuse opioids may be passed on to those who do not.

Figure 6. Kentucky Opioid Prescription Rate Projection (Per 100 Persons)

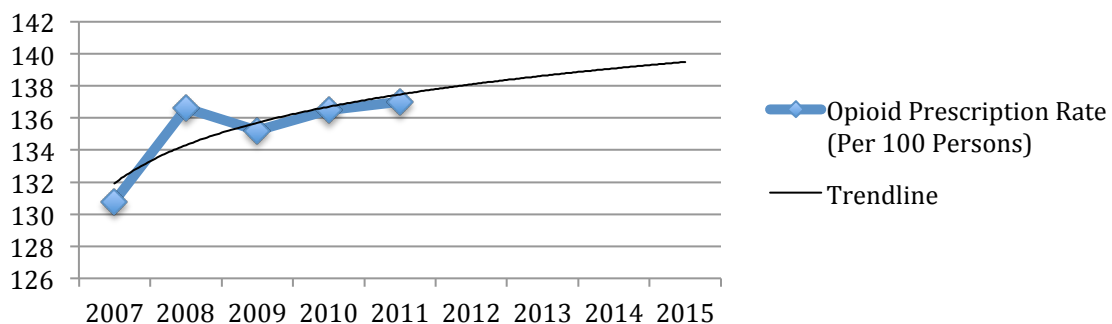
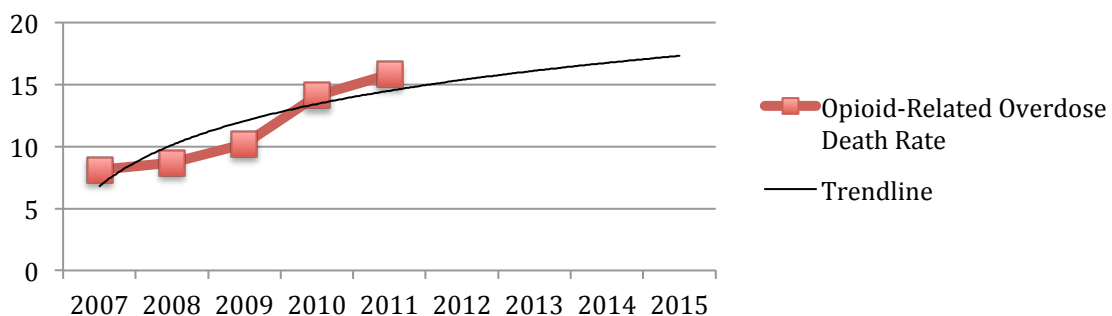


Figure 7. Kentucky Opioid-Related Overdose Death Rate Projection (Per 100,000 Persons)



Alternative 2:

Efficacy:

The TPSA of 2012 in Tennessee, another supply-side regulatory bill, similarly decreased Tennessee's prescription opioid rate from 138.5 prescriptions per 100 persons in 2011 to 114.9 in 2015. In addition, Tennessee also saw an increase in opioid-related overdose deaths from 16.6 per 100,000 persons, age adjusted, in 2011 to 22 in 2015.¹⁹

Freedom:

Again, the Tennessee policy restricted providers and therefore limited accessibility of opioid prescriptions to patients. It quite literally put a cap on the length of treatment providers were allowed to prescribe opioid analgesics to their patients. In this sense, it took away the right of the physician to do what they felt was best for the patient, given their clinical judgment.

Justice:

Similarly to KY HB1, the TPSA regulated providers, rather than those who might be actively abusing opioids. While it may have decreased the number of prescriptions being written, this did not help those who were already addicted. In fact, as briefly alluded to before, making it harder for addicts to obtain regulated prescriptions opioids may have incentivized them to seek out unregulated street forms of opioids, such as heroin.

Figure 8. Number of Opioid Prescriptions (Per 100 Persons)

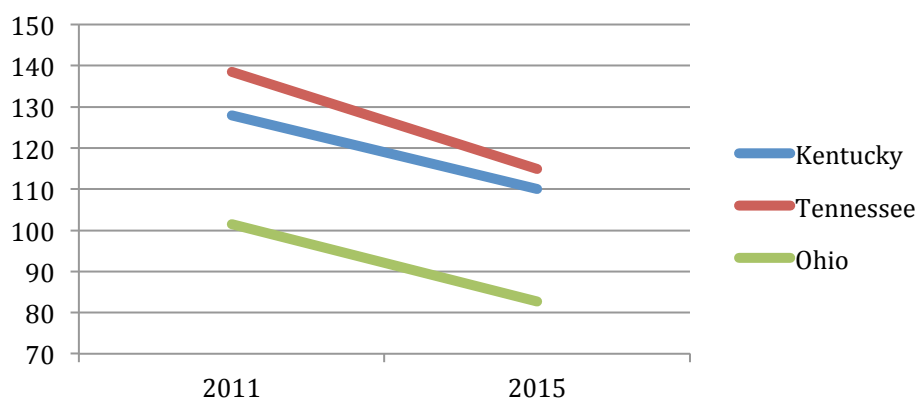
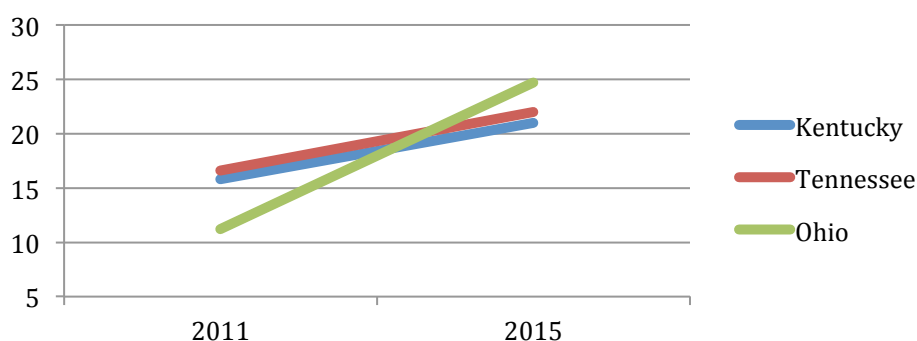


Figure 9. Number of Opioid-Related Overdose Deaths Per 100,000 Persons



Alternative 3:

Efficacy:

Ohio employed the Governor's Cabinet Opiate Action Team (GCOAT) and had success in decreasing the prescription of opioid pills, from 101.5 prescriptions per 100 persons in 2011 to 82.7 in 2015. However, it had issues similar to KY and TN with regards to increasing overdose death rates. In fact, opioid deaths in Ohio nearly

doubled from 11.2 opioid-related overdose deaths per 100,000 persons in 2011 to 24.7 in 2015.

Freedom:

This policy option, while still regulating prescription providers, included them in the discussion and leadership of the GCOAT. It relied not only on restrictions, but also employed education and options for addiction recovery.

Justice:

While GCOAT did place fairly heavy restrictions on the prescription of opioid analgesics by providers, it also gave providers an avenue to address addiction prevention and recovery with their patients. Those who were already addicted were educated also through public service announcements and school initiatives, allowing them to understand they had options for treatment.

Table 5: Number of Opioid Prescriptions Per 100 Persons <i>Source: CDC</i>		
	2011	2015
Kentucky	137	102.6
Tennessee	138.5	114.9
Ohio	101.5	82.7

Table 6: Rate of Opioid-Related Overdose Deaths per 100,000 Persons, Age Adjusted <i>Source: CDC</i>		
	2011	2015
Kentucky	137	102.6
Tennessee	138.5	114.9
Ohio	101.5	82.7

Table 7: Qualitative Outcomes Matrix					
Criteria	Alternatives				
		Base Case: KY HB 1	Alternative 1: Status Quo	Alternative 2: TPSA	Alternative 3: GCOAT
	Criterion 1: Efficacy	Minimally Satisfies Criterion	Does Not Satisfy Criterion	Minimally Satisfies Criterion	Minimally Satisfies Criterion
	Criterion 2: Freedom	Minimally Satisfies Criterion	Moderately Satisfies Criterion	Minimally Satisfies Criterion	Moderately Satisfies Criterion
	Criterion 3: Justice	Minimally Satisfies Criterion	Does Not Satisfy Criterion	Minimally Satisfies Criterion	Moderately Satisfies Criterion

Table 8: Quantitative Outcomes Matrix					
Criteria	Alternatives				
		Alternative 2: KY HB 1	Alternative 1: Null	Alternative 3: TPSA	Alternative 4: GCOAT
	Criterion 1: Efficacy (0.40)	$2 \times 0.4 = 0.8$	$1 \times 0.4 = 0.4$	$2 \times 0.4 = 0.8$	$2 \times 0.4 = 0.8$
	Criterion 2: Freedom (0.30)	$2 \times 0.3 = 0.6$	$3 \times 0.3 = 0.9$	$2 \times 0.3 = 0.6$	$3 \times 0.3 = 0.9$
	Criterion 3: Justice (0.3)	$2 \times 0.3 = 0.6$	$1 \times 0.3 = 0.3$	$2 \times 0.3 = 0.6$	$3 \times 0.3 = 0.9$
Total Score:		2.0	1.6	2.0	2.6

Using the Criteria Alternatives Matrix (see Tables 7 and 8), the policy action put forward by Ohio received the highest overall score, followed by Kentucky's and Tennessee's policies, which were tied. The lowest-scoring policy was that of the "status quo."

Discussion

Stop, Focus, Narrow, Deepen, Decide; Tell Your Story

As demonstrated above, Alternatives 2,3,4 were efficacious in decreasing the number of opioid prescriptions in their respective states. This is important because

it has been estimated that the rate of opioid prescriptions is related to the rate of addiction.²⁰ The majority of people addicted to opioid drugs were introduced via opioid pills.²¹ Not all, but most were legally prescribed those opioid pills.²¹ A common scenario where prescription opioids led to addiction is: a physician prescribes a patient oral opioid medication following surgery; after a period of time the patient experiences increased tolerance and dependence, becoming “addicted” to the opioid analgesia. Here is an illustration, based upon an actual patient of the author. Names have been changed to protect privacy.

The Creation of an Addict

Jane Doe is in a car accident and suffers back pain from her acute injury. She is prescribed IV opioid analgesia while inpatient in the hospital, and then oral opioid medication after her hospitalization. She is unable to wean herself from the pills, either because of tolerance or lack of other analgesic support, such as the use of non-steroidal anti-inflammatories like ibuprofen. She notices that when she decreases or stops the opioid medication, she begins to feel irritable and other symptoms of withdrawal. On top of that, she notices the same dose of medication isn’t “doing the trick,” and she must continually increase her dosage and/or frequency. In addition, she is unable to return to work due to her back pain and/or restrictions while under the influence of opioid medication. Because of this, she is extremely sensitive to changes in her levels of pain and symptoms of withdrawal, without work to distract her.

Her physician prescribes her pills for a while until he or she becomes uncomfortable, at which point Jane begs for, and is given, one more prescription. After that she is cut off. She however was unable to wean herself, so when her fingers grasp the last pill in the bottle, she wonders where and how she will get another dose. After all, she experiences real, intensely unpleasant symptoms when she goes without. So, she goes to other physicians, and if she's "lucky," they won't ask too many questions and will give her another script for the opioids. This tides her over until no physician is willing to prescribe her any more.

At this point, she becomes fraught and seeks out a friend-of-a-friend whom she has heard has pills for sale. She is shocked to find out that while her prescription pills cost around \$6 per pill, this dealer is charging \$50-\$100 per pill. After a while, she can no longer afford these black market pills, but is even more tolerant and dependent, requiring more and more pills to create the same effect and stave off symptoms of withdrawal. Her world begins to revolve around acquiring and using opioids. It becomes an obsession that takes over her life, and she could lose everything in her life to this fixation.

Supply-Side Restrictions

Legislators have been very willing to curtail the casual prescription of opioids. It seems clear that if physicians wouldn't prescribe so many pills, patients wouldn't become addicted at the rate they are. Having a law that limits opioid prescriptions makes it easier for physicians to "just say no" to prescribing any more than minimum doses and short courses of opioids. Legal restrictions give non-pain-

management physicians an “easy out” when they would have been uncomfortable prescribing these analgesics. “I’m sorry, I’m bound by this limitation in Kentucky” is easier to say than, “I don’t want to give you more.”

However, with supply-side regulations and drug prohibition has come diversion, which carries numerous dangers. Drugs obtained on the black market are unregulated and expensive. When demand increases, the pills become more expensive and/or adulterated to increase quantity. Black market oral opioid pills can cost 10 to 20 times the cost of their insurance-covered counterparts. In addition, substances can be expired, contaminated, or intentionally “cut” with other, less expensive chemicals to increase the bulk of supply.

Trading Pills for Needles

Users who are addicted to prescription opioid pills may turn to other forms of opioids when their supply is cut off or using pills becomes too expensive. When this happens, other, more serious complications may arise. The illustration of Jane, the patient-turned-addict begun above will continue to exhibit this phenomenon.

Seeing Jane’s desperation, the dealer informs her that he has another opioid option she could use. One that is much cheaper at only \$10 per hit: heroin. If one had asked Jane years earlier if she would ever use intravenous drugs, she may have laughed incredulously. But now, her body sends her severe and almost unbearable signals that she is dependent on the drug. Her mu opioid receptors have become more and more desensitized to binding with opioids, requiring that she take larger and more frequent doses to feel “normal,” let alone, “good.”

So she begins injecting the substance her dealer gives her. The concentrations vary with each “hit.” She has no way of knowing what exactly it is that she is injecting. Sometimes she feels the effects of other unknown substances. There is no quality control among illicit drug manufacturing and distributors. Whatever she is injecting, it certainly isn’t sterile. Neither are her needles.

She uses needles repeatedly, and sometimes without cleaning them in between uses. Sometimes, she borrows a needle from another user. Another user taught her how to inject into a vein, but it’s hard to do it to oneself, and sometimes she misses. Sometimes she simply injects it under her skin or into muscle, what she’s been told is called “skin popping.”

She begins to care little about anything else besides the next “hit.” Her body aches and anxiety overcomes her. Her heart races and her hands begin to tremble. She feels nauseated and vomits repeatedly; cramping abdominal pain doubles her over. She is restless and sweating, and maybe worst of all, she cannot sleep. It feels like a rapidly occurring flu each time she tries to abstain. However, all the pain, anxiety, tremulousness, and nausea disappear nearly instantaneously as she takes the next dose.

One time, she injects herself with a new batch from her dealer. She wakes up in an ambulance with paramedics yelling at her to wake up. She is lucid for the next hour as she sits in the hallway in the closest hospital’s emergency room. She loses consciousness again only to be awoken with a doctor and nurse standing over her. Narcan, the drug that reverses opioid overdose, doesn’t last as long as the opioid in her veins. She has to be watched for a few hours after that before she is released. A

few weeks after, she receives a bill from the hospital for an amount that equals tens of dozens of “hits,” and without a job, she has no way to pay even if she chose to.

A month later, she notices a large boil forming on her left shoulder. It continues to grow, though she has tried to drain it many times. It is followed by other sores that erupt on her arms. There are so many it is hard to even find a place to stick herself.

After weeks of dealing with the lesions, she begins to feel cold and clammy, lethargic, and short of breath. She takes her temperature and has a fever, so she calls an ambulance for help. Jane is brought to the hospital where she is diagnosed with endocarditis. Bacteria from the outside world entered her blood stream when she injected with a “dirty” needle, and traveled to and infected her heart. She has to be kept in the hospital for six full weeks on intravenous antibiotics in order to live. While there, she is told she is HIV positive and must begin a complex regimen of medications that she will be on for the rest of her life. When she is discharged she is told to follow up with a doctor in clinic, but can’t get to the appointment because she sold her car to pay for dope. She never fills her prescriptions for her HIV medications because she has no job, no money, and no insurance.

Unintended Consequences

Patients who become addicted to prescription opioid pills and are then cut off from them will turn to other avenues. Once their body has developed tolerance and dependence, their brain has quite literally been altered, by the desensitization of their opioid receptors. It is not exaggeration to say that at a certain level of

dependence human brains are reprogrammed to be drug-seeking machines. The symptoms of withdrawal are similar to those of influenza, minus the cough and congestion. They can be nearly unbearable for most people to endure. It is no wonder that addicted individuals turn to the cheaper and easily available injectable opioids.

Injectable opioids are fraught with danger, from the uncertainty of their contents, to their method of abuse. Confiscated heroin has been found to have many other ingredients added to it upon testing. Baby, and other, powders are added for bulk. Fentanyl, methamphetamines, and even benzodiazepines, along with other substances, have been found. In addition, drugs that are administered intravenously in the hospital are carefully regulated, stored, mixed, and infused in such a way to preserve sanitation.

The use of skin-popping and other unsterilized routes of injection, including sharing and re-using “dirty” needles carries its own consequences, regardless of what is being injected. Soft tissue and skin infection in IV drug users is a known complication.²² Septic emboli, tiny masses of infection that block off arteries, causes necrosis of whatever tissue they were supplying. Endocarditis, wherein bacteria travel to the heart and disrupt the functioning of the heart valves is fatal without treatment, and leaves lasting consequences even when the original infection is cleared. Sharing needles transmits deadly infectious diseases like HIV and Hepatitis C, and their sequelae are devastating.²³

It has been shown that IV drug users utilize the healthcare system at higher rates than patients who are not.²³ These patients constitute a considerable burden on the healthcare economy, as they are often quite complex and often uninsured.²³

Considering all this, it is important to consider the unintended consequence of supply-side regulations pushing addicts towards black market and IV drugs.

Conclusion/ Recommendation

It appears that all of the above-mentioned policies, excepting Alternative 1, employed chiefly supply-side regulations and restrictions. While these policies have been associated with decreased opioid prescription rates, increased opioid-related overdose deaths were also observed. This was certainly not the intent, but insufficient attention was given to those citizens that were already dependent on opioids at the time of legislation. Only in the case of GCOAT in Ohio were addiction recovery measures taken.

Thought must be given to those who are already addicted, as it has been shown that they may divert to street drugs when cut off from prescriptions. In order to reduce opioid-related overdoses, drug treatment options should be brought to the forefront. Safeguards should be put in place to prevent the spread of blood-borne illnesses and other infective sequelae of intravenous drug use, such as clean syringe exchanges. Protections should be given to encourage those who witness an overdose to call emergency services. Naloxone, the opioid-reversal medication, should be made readily available to first responders and those who receive opioid prescriptions.

Since 2015, Kentucky has implemented more comprehensive plans to quell the opioid epidemic.²⁴ Time will tell if these measures are capable of reducing what really matters- saving constituents from the consequences of opioid addiction and overdose deaths.

Final Recommendations

In creating policy to address the Opioid Epidemic, four objectives should be pursued:

1. Decrease unnecessary prescription of opioid medication
 - a. Utilize the knowledge and partnership of physicians in creating guidelines for the proper prescription of these medications
 - b. Support providers in educating their patients on the risks of opioid prescription usage
 - c. Incentivize use of non-opioid pain management techniques
2. Provide avenues of treatment for those citizens suffering from addiction
 - a. Provide comprehensive addiction treatment and recovery facilities and programs at little cost to the patient. The costs of addiction and its complications far outweigh the costs of providing these services.
 - b. Establish addiction recovery clinics that dispense buprenorphine and methadone in areas of high opioid abuse rates
3. Employ strategies to reduce the complications of intravenous drug use
 - a. Establish clean syringe exchange programs in areas of high opioid abuse rates

4. Equip first responders and average citizens with the tools to combat drug overdose and prevent overdose deaths
 - a. Provide naloxone to all first responders, patients with an opioid prescription, and to volunteers that request it
 - b. Give legal immunity to those that report overdoses in order to encourage swift treatment

A comprehensive opioid policy should be employed in order to do what matters most: reduce the morbidity and mortality of opioid abuse and addiction.

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